



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3410-N]

Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee - September 22, 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces a virtual public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) ("Committee") will be held on Wednesday, September 22, 2021. The MEDCAC panel will examine relevant health outcomes in studies for cerebrovascular disease treatment with a particular focus on new technologies of interest to CMS. Given the increased emphasis on new and innovative medical products for treating diseases that have few proven therapies, studies on certain medical technologies have focused on intermediate and surrogate outcomes rather than longer-term data. As a result, there are more frequent evidence gaps with respect to the clinically meaningful health outcomes for CMS beneficiaries, and these gaps impact our assessments of medical technologies. The MEDCAC panel will examine the growing challenges associated with the decreased level of evidence of certain new and innovative technologies. By voting on specific questions, and by their discussions, MEDCAC panel members will advise CMS about the ideal health outcomes in research studies of cerebrovascular disease treatment technologies, appropriate measurement instruments and follow-up durations to help to provide clarity and transparency of National Coverage Analyses (NCAs). This meeting is open to the public in accordance with the Federal Advisory Committee Act.

DATES: Meeting Date: The virtual meeting will be held on Wednesday, September 22, 2021 from 8:00 a.m. until 4:30 p.m., Eastern Daylight Time (EDT).

Deadline for Submission of Written Comments: Written comments must be received at the email address specified in the **ADDRESSES** section of this notice by 5:00 p.m., Eastern Daylight Time (EDT), on Monday, August 23, 2021. Once submitted, all comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker and to submit PowerPoint presentation materials and writings that will be used in support of an oral presentation is 5:00 p.m., EDT, on Monday, August 23, 2021. Speakers may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the email address specified in the **ADDRESSES** section of this notice.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via e-mail to MedCACpresentations@cms.hhs.gov section of this notice by Monday, August 23, 2021.

Deadline for All Other Attendees Registration: Individuals who want to join the meeting may register online at

https://cms.zoomgov.com/webinar/register/WN_eJmuvv1UTImALOSXqhKmPQ
4:30 p.m. EDT, on Wednesday, September 22, 2021.

Webinar and Teleconference Meeting Information: Teleconference dial-in instructions, and related webinar details will be posted on the meeting agenda, which will be available on the CMS website <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. Participants in the MEDCAC meeting will require the following: a computer, laptop or smartphone where the Zoom application needs to be downloaded; a strong Wi-Fi or an internet connection and access to use

Chrome or Firefox web browser and a webcam if the meeting participant is scheduled to speak or make a presentation during the meeting.

Deadline for Submitting a Request for Special Accommodations: Individuals viewing or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should send an email to the MEDCAC Coordinator as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5:00 p.m., EDT on Friday, August 27, 2021.

ADDRESSES: Due to the current COVID-19 public health emergency, the Panel meeting will be held virtually.

FOR FURTHER INFORMATION CONTACT: Tara Hall, MEDCAC Coordinator, via e-mail at Tara.Hall@cms.hhs.gov or by phone 410-786-4347.

SUPPLEMENTARY INFORMATION:

I. Background

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), is advisory in nature, with all final coverage decisions resting with CMS. MEDCAC is used to supplement CMS' internal expertise. Accordingly, the advice rendered by the MEDCAC is most useful when it results from a process of full scientific inquiry and thoughtful discussion, in an open forum, with careful framing of recommendations and clear identification of the basis of those recommendations. MEDCAC members are valued for their background, education, and expertise in a wide variety of scientific, clinical, and other related fields. (For more information on MEDCAC, see the MEDCAC Charter (<http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/medcaccharter.pdf>) and the CMS Guidance Document, *Factors CMS Considers in Referring Topics to the MEDCAC*

(<http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=10>).

II. Meeting Topic and Format

This notice announces the Wednesday, September 22, 2021, virtual public meeting of the Committee. The MEDCAC panel will examine relevant health outcomes in studies for cerebrovascular disease treatment with a particular focus on new technologies of interest to CMS. Given the increased emphasis on new and innovative medical products for treating diseases that have few proven therapies, studies on certain medical technologies have focused on intermediate and surrogate outcomes rather than longer-term data. As a result, there are more frequent evidence gaps with respect to the clinically meaningful health outcomes for CMS beneficiaries, and these gaps impact our assessments of medical technologies. The MEDCAC panel will examine the growing challenges associated with the decreased level of evidence of certain new and innovative technologies. By voting on specific questions, and by their discussions, MEDCAC panel members will advise CMS about the ideal health outcomes in research studies of cerebrovascular disease treatment technologies, appropriate measurement instruments and follow-up durations to help to provide clarity and transparency of National Coverage Analyses (NCAs).

Background information about this topic, including panel materials, is available at <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. Electronic copies of all the meeting materials will be on the CMS website no later than 2 business days before the meeting. We encourage the participation of organizations with expertise in the appraisal of the state of evidence for the use of services and technologies to diagnose and treat patients with cerebrovascular disease. This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. Time allotted for each

presentation may be limited. If the number of registrants requesting to speak is greater than what can be reasonably accommodated during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 30, 2021. Your comments must focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following web site prior to the meeting: <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed. Speakers presenting at the MEDCAC meeting must include a full disclosure slide as their second slide in their presentation for financial interests (for example, type of financial association - consultant, research support, advisory board, and an indication of level, such as minor association < \$10,000 or major association > \$10,000) as well as intellectual conflicts of interest (for example, involvement in a federal or nonfederal advisory committee that has discussed the issue) that may pertain in any way to the subject of this meeting. If you are representing an organization, we require that you also disclose conflict of interest information for that organization. If you do not have a PowerPoint presentation, you will need to present the full disclosure information requested previously at the beginning of your statement to the Committee.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the

members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone number(s), and e-mail address. You will receive a registration confirmation with instructions for your participation at the virtual public meeting.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Chief Medical Officer and Director of the Center for Clinical Standards and Quality for the Centers for Medicare & Medicaid Services (CMS), Lee A. Fleisher, having reviewed and approved this document, authorizes Lynette Wilson, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: July 27, 2021.

Lynette Wilson,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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